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Registration Decision RD2011-06

1,4-Dimethylnaphthalene

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Registration Decision for 1,4-Dimethylnaphthalene

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the Pest Control Products Act, and Regulations, is granting full registration for the sale and use of 1,4SIGHT Technical, 1,4SHIP, 1,4SIGHT and 1,4SEED, containing the technical grade active ingredient 1,4-dimethylnaphthalene, as a potato sprout inhibitor.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2010-26, *1,4-Dimethylnaphthalene* on which the PMRA received no comments. This Registration Decision[2] describes this stage of the PMRA's regulatory process for 1,4-dimethylnaphthalene and summarizes the Agency's decision and the reasons for it. This decision is consistent with the proposed registration decision stated in PRD2010-26, *1,4-Dimethylnaphthalene*.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-26, *1,4-Dimethylnaphthalene* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.
2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.
3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.
4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is 1,4-Dimethylnaphthalene?

1,4-Dimethylnaphthalene is a plant growth regulator belonging to the chemical family of alkyl-substituted naphthalenes. This compound is a naturally occurring plant biochemical in potatoes. It has been identified as a potato dormancy enhancer, delaying sprouting. The mode of action of 1,4-dimethylnaphthalene is unknown, but is likely hormonally based.

1,4SIGHT and 1,4SEED contain the active ingredient at 988 g/L and 998 g/L, respectively. 1,4SHIP contains 1,4-dimethylnaphthalene at 63.8% (equivalent to 96 g active ingredient per can). 1,4SIGHT and 1,4SEED are formulated as liquids (aerosol grade), while 1,4SHIP is formulated as a ready-to-use aerosol.

Health Considerations

Can Approved Uses of 1,4-Dimethylnapthalene Affect Human Health?

1,4-Dimethylnaphthalene is unlikely to affect human health when used according to label directions.

Exposure to 1,4-dimethylnaphthalene may occur when entering the treatment site during or after application. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

1,4-Dimethylnaphthalene is of low acute toxicity by the oral, dermal, and inhalation routes. It is slightly irritating to eyes, mildly irritating to skin, and is not a skin sensitizer. Hazard statements alerting users to the irritation potential of 1,4-dimethylnaphthalene are required on the product labels. There is no information available in the published literature that suggests 1,4-dimethylnaphthalene is carcinogenic, genotoxic, neurotoxic or a developmental/reproductive toxicant.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Dietary risk to humans is not of concern from the uses of the formulations because 1,4-dimethylnaphthalene is a naturally occurring potato sprout inhibitor, has a low toxicity profile, and is naturally broken down. Moreover, residue levels are likely to be diminished further by washing, peeling and cooking.

These end-use products are used in a contained treatment area and not in proximity to water. No risk due to exposure from drinking water is anticipated.

Occupational Risks From Handling 1,4SHIP, 1,4SIGHT or 1,4SEED

Risks are not of concern when the products are used according to label directions, which include protective measures.

Due to the closed and automated nature of the application system, applicator exposure is expected to be minimal. Exposure during re-entry activities represents a high exposure scenario and the primary routes of exposure are inhalation and dermal, but exposures are well mitigated by precautionary measures, including the requirement for applicators to wear personal protective equipment and follow precautionary statements.

There is no bystander exposure expected from the use pattern, as no people are allowed inside an enclosed storage facility during treatment.

Use directions and mitigative measures on the labels are considered adequate to protect individuals from any risks from occupational exposure.

Environmental Considerations

What Happens When 1,4-Dimethylnaphthalene Is Introduced Into the Environment?

Environmental risks are not of concern due to limited environmental exposure.

1,4-Dimethylnaphthalene is a chemical substance that occurs naturally in potatoes. 1,4-Dimethylnaphthalene is highly volatile and has a low solubility in water. It is expected to degrade rapidly in the environment through photochemical reactions (with hydroxyl radicals) or microbial activity. Environmental exposure from the indoor use of this product is expected to be limited.

1,4-Dimethylnaphthalene is not toxic to birds on an acute oral basis. Based on available data, there is no concern about inhalation risk to wild birds nesting or roosting in the vicinity of storage facilities. 1,4-Dimethylnaphthalene is toxic to aquatic organisms. However, based on the use patterns, no or very limited exposure of aquatic ecosystem is expected.

Value Considerations

What Is the Value of 1,4SHIP, 1,4SIGHT or 1,4SEED?

1,4-Dimethylnaphthalene is a naturally occurring plant biochemical in potatoes. It is applied to potatoes in storage as a dormancy enhancer, thus delaying sprouting along with reducing respiration and maintaining tuber firmness.

Effective sprout inhibition can be achieved with a single or multiple applications of 1,4-dimethylnaphthalene. 1,4-Dimethylnaphthalene is a volatile compound and can dissipate easily, requiring subsequent re-application in some situations. The effects of 1,4-dimethylnapthalene are reversible and, therefore, this product can be used on seed potatoes.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the labels of 1,4SHIP, 1,4SIGHT and 1,4SEED to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Signal wording and appropriate precautionary measures are required to address the mild skin irritation hazard. Hazard statements and appropriate precautionary measures are also required to address possible eye and respiratory irritation hazards.

Workers must wear coveralls over a long-sleeved shirt, long-pants, shoes, socks, protective eyewear, and chemical resistant gloves during application or during clean-up and maintenance activities. Storage areas must be ventilated for at least 30 minutes or completely ventilated before allowing workers to enter for normal activities. If entering storage areas before full ventilation, workers must wear coveralls over long-sleeved shirt, long-pants, shoes, socks, face-sealing goggles, chemical resistant gloves, and respiratory protection.

Environment

A hazard statement is required to address toxicity to aquatic organisms.

Value

An advisory statement is required to address possible yield reduction and shift to smaller tubers when the products are applied to seed potatoes. An advisory statement is also required to address the risk of undesirable taste characteristics in treated potatoes, which can be mitigated by monitoring residue levels to ensure they do not exceed 1 ppm prior to marketing.

Other Information

The relevant test data on which the decision is based (as referenced in this document and Proposed Registration Decision PRD2010-26, *1,4-Dimethylnaphthalene*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act*.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number: 1978278
Reference: 2010, Determination of storage stability and corrosion characteristics of 1,4-dimethylnaphthalene (1,4-DMN), Data Numbering Code: 3.5.10 Confidential Business Information.